Application No.: 10/646267 Docket No.: CCI-007USDV

## **REMARKS**

Claims 1-8 and 11-12 were pending in the instant application as of the issuance of the Office Action dated May 10, 2006. By the current Amendment to Claims, claims 1, 3, 4, 6-8 and 12 have been amended and new claim 13 has been added.

Support for the amendments to claims 1, 6 and 7 and for the introduction of new claim 13 can be found throughout the specification, for example, at page 9, line 25 to page 10, line 8, and at page 14, lines 3-24, and in the claims as originally filed. Claims 3, 4, 8 and 12 have been amended merely to attend to formalities, for example, to attend to antecedent basis. No new matter has been added by the foregoing amendments or the introduction of new claim 13.

Applicants respectfully request that the aforementioned amendments be entered. Applicants note that the foregoing amendments have been made in order to expedite examination and in no way should be construed as acquiescence to the validity of the rejections set forth in the Office Action. Following entry of the foregoing amendments, claims 1-8 and 11-13 will remain pending.

## Restriction Requirement

In the response to the first Restriction Requirement as set forth in the Office Action of January 6, 2006, Applicants elected to prosecute the claims of Group I (Claims 1-8 and 11-12, drawn to a method of inhibiting activity). In addition, Applicants elected the following species for search purposes only: cdk4 as the G1 cdk; a single pure compound as the "substance"; and Rb phosphorylation as the specific G1 cdk "activity" to be inhibited.

According to the Office Action of May 10, 2006, claims 1-8 and 11-12 are subject to a further restriction requirement. The Examiner has required restriction, under 35 U.S.C. § 121, between the following inventions in the above-identified application:

Group III: Claims 1-5, 8, 11-12, drawn to a method of inhibiting an activity of a G1 cdk comprising the use of a "substance that includes a peptide," and wherein a carrier molecule is neither suggested nor required;

Group IV: Claims 6-7, drawn to a method of inhibiting an activity of a G1 cdk comprising the use of a "substance that includes a peptide," and wherein the peptide is coupled to a carrier molecule; and

Application No.: 10/646267 Docket No.: CCI-007USDV

Group V: Claim 12, drawn to a method of determining whether, and to what degree, cell cycle arrest may have occurred.

In response to the Restriction Requirement set forth in the Office Action dated May 10, 2006, Applicants hereby elect, *with traverse*, to prosecute the claims of Group III (Claims 1-5, 8, 11-12, drawn to a method of inhibiting an activity of a G1 cdk comprising the use of a "substance that includes a peptide," and wherein a carrier molecule is neither suggested nor required).

The Examiner requires restriction between Group III and Group IV on the grounds that:

[g]roups III and IV are distinct. It is entirely possible that the genus of claim 1 is novel, but that, at the same time, the invention of claims 6-7 is not. It may be the case that applicants are the first to discover that an activity of a G1 cdk can be inhibited when contacted with a peptide that consists of 40 amino acids or less. But that does not mean that claim 6 is necessarily novel. Claim 6 could be interpreted to include proteins of any molecular weight. It may well be the case that it was known in the art that any of several proteins could inhibit the activity of a G1 cdk, and which proteins contain the subsequence identified in claim 1. Thus, if the nature of the 'carrier molecule' is not specified, novelty of the Group II claims will not necessarily extend to the group IV claims.

Applicants traverse the foregoing rejection on the ground that claims 1-8 and 11-12, as amended, form a single inventive concept and therefore possess unity of invention. Applicants note that claim 1, as amended, is directed to the use of a substance which is selected from the group consisting of a peptide fragment of 40 amino acids or less of p21, a derivative thereof, the peptide fragment or derivative thereof coupled to a non-peptidyl coupling partner and the peptide fragment or derivative thereof coupled to a non-p21 peptide sequence. Applicants note that in view of the recitation of the nature of the carrier molecule as being either a non-peptidyl coupling partner, or, alternatively, a non-p21 peptide sequence, and further in view of the recitation of the peptide fragment as a fragment of p21, a finding of novelty of the use of the peptide fragment necessitates a finding of novelty of claims directed to the use of peptide fragments linked to the specified coupling partners. Accordingly, Applicants submit that at least Groups III and IV possess unity of invention and, minimally, these two groups should be rejoined for the purpose of initial examination.

Applicants respectfully request withdrawal of the Restriction Requirement as applied to Groups III and IV. Applicants' election of the foregoing subject matter is without prejudice to Applicants' rights to pursue non-elected subject matter in other applications. Furthermore,

Application No.: 10/646267 Docket No.: CCI-007USDV

Applicants reserve the right to traverse the restriction between the non-elected groups in this or a separate application.

The Examiner has further required the election of a single species as set forth below:

- a) one of the following: (i) the elected substance is identical to the peptide of 40 amino acids (or less) that is described in claim 1, or (ii) the elected substance contains at least one atom that is not present in the peptide of 40 amino acids (or less) that is described in claim 1; and
- b) a specific substance that falls within the scope of claim 1, in which the peptide (of 40 amino acids or less) is specifically identified.

Accordingly, Applicants hereby elect, *for search purposes only*, the elected substance is identical to the peptide of 40 amino acids (or less) that is described in claim 1; and residues 16-35 of p21<sup>WAF</sup> as a specific substance that falls within the scope of claim 1. In this regard, it is Applicants' understanding that upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. §1.141 *et seq*. Accordingly, upon allowance of the elected species, Applicants request that the search be extended to the remaining species. Applicants' election of the foregoing species is without prejudice to Applicants' rights to pursue non-elected subject matter in this and other applications.

Application No.: 10/646267 Docket No.: CCI-007USDV

## **SUMMARY**

Applicants respectfully submit that the above-identified application is in condition for allowance. If a telephone conversation with Applicants' attorney would expedite prosecution of the above-identified application, the Examiner is urged to call Applicants' Attorney at (617) 227-7400.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the present filing to Deposit Account No. 12-0080 under Order No. CCI-007USDV, from which the undersigned is authorized to withdraw.

Dated: September 11, 2006

Respectfully submitted,

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